

# Enzymatic Therapy

NATURAL MEDICINES®

January 24, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

FFB 06 2004

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Black Cohosh (Cimicifuga racemosa) Root Extract for relief of menopausal symptoms*	Black Cohosh (Cimicifuga racemosa) Root Extract Rand Rhizome Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-24-04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux

Michael P. Devereux  
Chief Financial Officer

AM/PM Menopause Formula 20c

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph 920 469-1313

Fax 888-570-6460

www.enzy.com

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13 795

# Enzymatic Therapy

NATURAL MEDICINES®

January 24, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Ginseng (Panax ginseng) Root Extract Phytosome™ to support energy levels and relieve menopausal symptoms.*	Ginseng (Panax ginseng) Root Extract Phytosome™

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

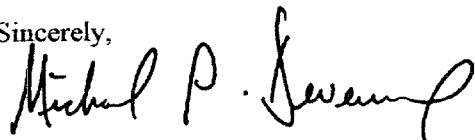
By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/24/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

AM/PM Menopause Formula 21e

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

# Enzymatic Therapy

NATURAL MEDICINES®

January 25, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Green Tea (Camellia sinensis) Leaf Extract to support women's health and energy levels.*	Green Tea (Camellia sinensis) Leaf Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

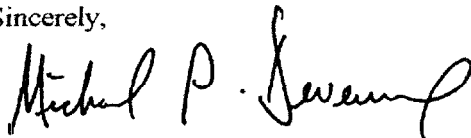
Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

1/25/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

January 27, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Effective in relieving hot flashes*	Ginseng (Panax ginseng) Root Extract Phytosome™

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

1/27/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Financial Officer

AM/PM Menopause Formula 26a

# EnzymaticTherapy

NATURAL MEDICINES®

January 27, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740


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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Enhances endurance and resistance to stress*	Ginseng (Panax ginseng) Root Extract Phytosome™

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

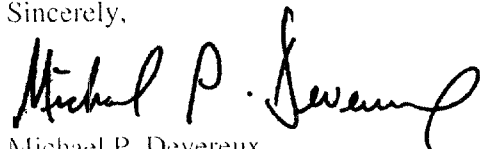
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-27-04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

January 28, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	An ergogenic aid, effective in supporting overall health, performance and reducing fatigue*	Green Tea (Camellia sinensis) Leaf Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

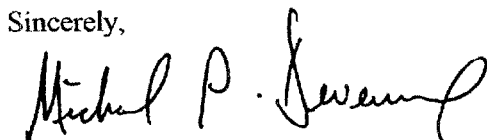
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/28/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

AM/PM Menopause Formula 28\*

# Enzymatic Therapy

NATURAL MEDICINES®

January 28, 2004

Office of Nutritional Products, Labeling &  
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Supports improved mood and relaxation*	Black Cohosh (Cimicifuga racemosa) Root Extract and Rhizome Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

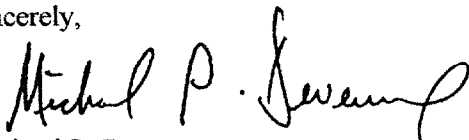
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/28/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

AM/PM Menopause Formula 29c

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

# Enzymatic Therapy

NATURAL MEDICINES®

January 28, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Supports improved mood and relaxation*	Ginseng (Panax ginseng) Root Extract Phytosome™

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

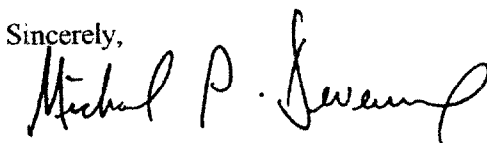
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/29/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

AM/PM Menopause Formula 30c

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com



# Enzymatic Therapy

NATURAL MEDICINES®

January 28, 2004

Office of Nutritional Products, Labeling &  
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Supports improved mood and relaxation*	L-Theanine

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

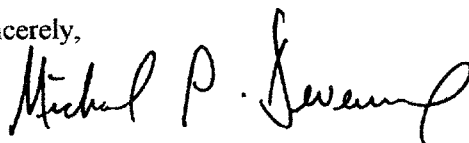
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/28/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

January 29, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Traditionally used for sleep aid; Effective when combined with valerian*	Hops (Humulus lupulus) Flower Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

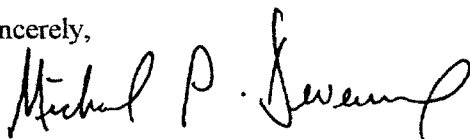
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/29/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

AM/PM Menopause Formula 32e

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph. 920-469-1313

Fax: 888-570-6460

www.enzy.com

# Enzymatic Therapy

NATURAL MEDICINES®

January 29, 2004

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College Park, MD 20740

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	A series of open clinical studies in more than 800 subjects demonstrated good efficacy of black cohosh extract in relieving hot flashes.*	Black Cohosh (Cimicifuga racemosa) Root and Rhizome Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

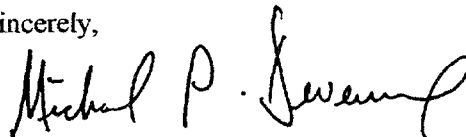
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/29/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

AM/PM Menopause Formula 34\*

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

# Enzymatic Therapy

NATURAL MEDICINES®

January 29, 2004

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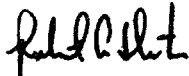
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Several double blind, placebo- controlled studies also demonstrate that black cohosh extract is beneficial in relieving menopausal symptoms.*	Black Cohosh (Cimicifuga racemosa) Root and Rhizome Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.



By: \_\_\_\_\_

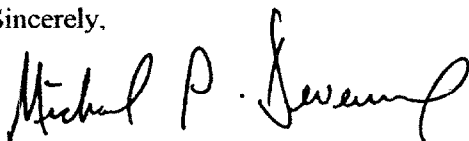
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/29/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

AM/PM Menopause Formula 35a

# Enzymatic Therapy

NATURAL MEDICINES®

January 29, 2004

Office of Nutritional Products, Labeling &  
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	A randomized, placebo-controlled, double-blind study compared women who took standardized black cohosh extract with women taking conjugated estrogen or a placebo. At the end of the study, the women taking the standardized black cohosh extract showed improvement relative to the placebo as measured by the Kupperman Menopausal Index, the Hamilton Anxiety Scale, and the maturation index of vaginal epithelium.* No clear improvement of menopausal complaints was observed in the control group. This study demonstrated clinical and statistical improvement of symptoms by the women taking the standardized black cohosh extract.*	Black Cohosh (Cimicifuga racemosa) Root and Rhizome Extract

# Enzymatic Therapy

NATURAL MEDICINES®

January 29, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	A double-blind, placebo-controlled study with 384 symptomatic postmenopausal women showed a tendency towards slightly better overall symptom relief, and a significant improvement in mood and well-being after supplementation of ginseng extract for 16 weeks.*	Ginseng (Panax ginseng) Root Extract Phytosome™

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

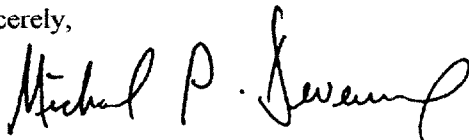
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/29/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

AM/PM Menopause Formula 37e

# Enzymatic Therapy

NATURAL MEDICINES®

January 30, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740


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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Green tea is a dried product of the fresh shoot of the tea plant (Camellia sinensis) from which numerous biological activities have been reported. One component is caffeine. Caffeine has been extensively studied as an ergogenic (energy producing) aid. It has shown consistent ergogenic effects for the support of overall health, stamina, and the reduction of fatigue.*	Green Tea (Camellia sinensis) Leaf Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.



By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/30/04

# Enzymatic Therapy

NATURAL MEDICINES®

January 30, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	A 1998 study indicates that green tea supports women's breast health in a variety of ways.*	Green Tea (Camellia sinensis) Leaf Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

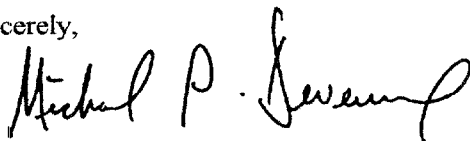
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/30/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

AM/PM Menopause Formula 39p



# Enzymatic Therapy

NATURAL MEDICINES®

January 30, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Green tea is a rich source of flavonoids and polyphenols, namely, catechins and flavonols. The catechins, also know as tea polyphenols, which occur in significant quantities in green tea, are catechin, epicatechin, galliccatechin, epigallocatechin, epicatechin gallate, and epigallocatechin gallate (EGCG). A study has indicated that EGCG supports healthy breast cell development.*	Green Tea (Camellia sinensis) Leaf Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

*Robert Doster*

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-30-04

825 Challenger Drive


Green Bay, WI 54311-8328

Ph: 888-426-1111

Fax: 888-570-6460

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" being the most prominent.

Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

January 30, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

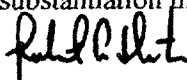
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Valerian (Valeriana officinalis) has been reported to have sleep inducing and calming effects in in-vivo studies and clinical trials.*	Valerian (Valeriana officinalis) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.



By: \_\_\_\_\_

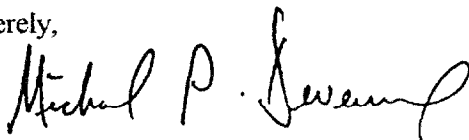
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/30/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

January 31, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	A placebo-controlled, crossover trial of 128 volunteers reported 400 mg of valerian extract at bedtime led to improved sleep quality, decreased sleep latency, and reduced the number of night awakenings.*	Valerian (Valeriana officinalis) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

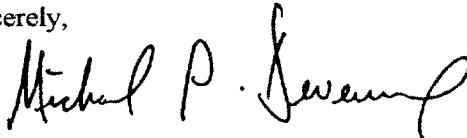
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/31/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

  
Michael P. Davenport  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

January 31, 2004

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Dietary Supplements, HFS 810  
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	In a double-blind, cross-over, placebo-controlled trial, subjective sleep latency and wake time after sleep-onset were reduced by more than half after a 900 mg dose, with a smaller effect after 450 mg.* One electroencephalographical (EEG) study reported 135 mg of aqueous, dried extract of valerian, taken three times daily, improved delta sleep and decreased stage 1 sleep.*	Valerian (Valeriana officinalis) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

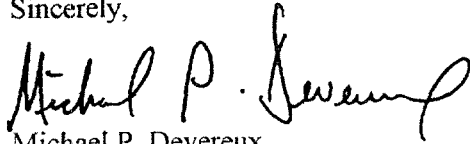
Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

1/31/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" and last name "Devereux" clearly legible, and "P." in the middle.

Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

February 1, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
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College Park, MD 20740

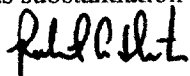
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Recently, two human trials also demonstrated that valerian extract was effective in improvement of sleep structure and perception in subjects.* In general, clinical studies with valerian extracts suggest that the mild sleep-inducing effect of valerian decreases sleep latency and improves sleep quality.*	Valerian (Valeriana officinalis) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.



By: \_\_\_\_\_

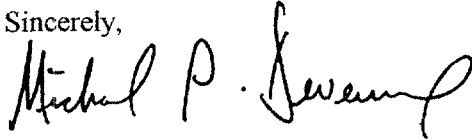
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/1/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" being the most prominent.

Michael P. Devereux  
Chief Financial Officer



# Enzymatic Therapy

NATURAL MEDICINES®

February 1, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	In clinical trials, L-theanine causes significant increases of certain neurotransmitter concentrations in brain, which promotes muscle relaxation and improves sleep.*	L-Theanine

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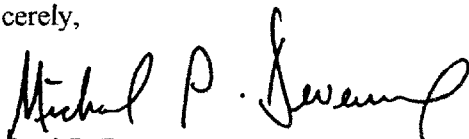
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Hops have been used for centuries for gastrointestinal health support, and have more recently been used to support healthy sleep.*	Hops (Humulus lupulus) Flower Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

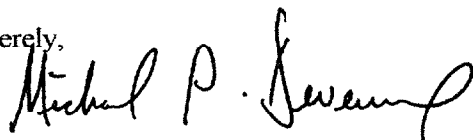
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/1/04

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Sincerely,



Michael P. Devereux  
Chief Financial Officer

AM/PM Menopause Formula 46a

# Enzymatic Therapy

NATURAL MEDICINES®

February 1, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Hops have been demonstrated to induce sleep.*	Hops (Humulus lupulus) Flower Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

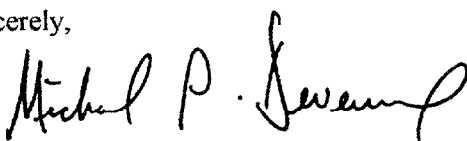
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Title: Senior Vice President of Scientific Affairs

Date: 2/1/04

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Sincerely,



Michael P. Devereux  
Chief Financial Officer

AM/PM Menopause Formula 47a

# Enzymatic Therapy

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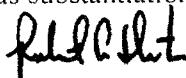
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	To date, there is no definitive published data available to clearly describe the process; however, forty years of clinical studies on a standardized black cohosh extract show efficacy in the relief of hot flashes, profuse sweating, occasional sleeplessness and for support of mood.*	Black Cohosh (Cimicifuga racemosa) Root and Rhizome Extract

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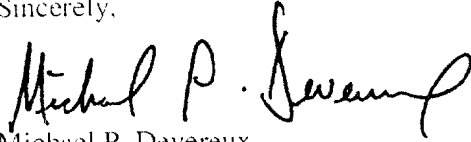
  
By: \_\_\_\_\_

Robert Doster  
Title: Senior Vice President of Scientific Affairs

Date: 2/1/04

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Michael P. Devereux  
Chief Financial Officer